

## Complete Summary

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### GUIDELINE TITLE

Smoking cessation.

### BIBLIOGRAPHIC SOURCE(S)

Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p. [1 reference]

## COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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## SCOPE

### DISEASE/CONDITION(S)

Tobacco dependence

### GUIDELINE CATEGORY

Counseling

Screening

Treatment

### CLINICAL SPECIALTY

Family Practice

Internal Medicine

### INTENDED USERS

Health Care Providers

Physicians

## GUIDELINE OBJECTIVE(S)

To provide a systematic framework for care providers to assist patients in smoking cessation

## TARGET POPULATION

Adolescent and adult smokers

## INTERVENTIONS AND PRACTICES CONSIDERED

### Screening

1. Assessment of smoking status
2. Assessment of readiness to quit

### Treatment

1. Advice and counseling:
  - Brief clinic intervention model known as "4-A" model: Ask, Advise, Assist, Arrange
  - Motivational intervention using "4 R's": Relevance, Risks, Rewards, Repetition
2. Pharmacotherapy: First-Line:
  - Transdermal nicotine patch, such as Nicoderm CQ, Nicotrol, generic nicotine transdermal patches
  - Nicotine gum (polacrilex), such as Nicorette, generic nicotine polacrilex (Watson)
  - Nicotine nasal spray, such as Nicotrol NS
  - Nicotine inhaler, such as Nicotrol inhaler
  - Bupropion hydrochloride SR (Zyban®)
3. Pharmacotherapy: Second-Line:
  - Clonidine
  - Nortriptyline
4. Advice on weight gain after smoking cessation
5. Follow-up to prevent relapse

## MAJOR OUTCOMES CONSIDERED

Efficacy of treatment as evidenced by smoking cessation rates

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this project was conducted prospectively. The development of the initial University of Michigan Health System Smoking Cessation Guideline began with a literature search performed by the Agency for Health Care Policy and Research (AHCPR) and reported in Smoking Cessation, Clinical Practice Guideline Number 18 (AHCPR Publication No. 96-0692, 1996) reviewed literature from 1975-1994. The guideline team then updated the AHCPR literature search through a Medline search of literature 1995-1997. This search used the major keywords of: smoking/[prevention & control], smoking cessation, tobacco use disorder/[prevention & control, rehabilitation]. The search was restricted to literature that was also referenced as either guidelines or controlled trials, as studies of humans, and as published in English. The search was conducted in components each keyed to a specific causal link in a formal problem structure (available upon request). The search was a single cycle.

In 2000, the U.S. Public Health Service published the document "Treating Tobacco Use and Dependence" - an update of the 1996 AHCPR smoking cessation clinical practice guideline. This updated document reviewed literature from 1995 through 1998. The current update of the University of Michigan Health System smoking cessation guideline began with the literature search performed by the U.S. Public Health Service for its update. This literature was supplemented with more recent publications known to the authors.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence that reflect the best available literature in support of an intervention or test:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses  
Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, duration, and instructions for nicotine replacement therapies and bupropion and cost of drugs, counseling and motivational interventions, and considerations for special populations (pregnant patients, adolescents, racial and ethnic minorities, patients with psychiatric co-factors, non-cigarette tobacco users, gender concerns, older smokers, hospitalized smokers).

The levels of evidence [A-D] are defined at the end of the Major Recommendations.

- Assessment:
  - ASK all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the medical record.
- Treatment:
  - ADVISE all smokers to seriously consider making a quit attempt using a clear and personalized message. Advice as brief as 3 minutes is effective [C].
    - Offer motivational intervention to those not yet ready to quit using the 4 "R's" - Relevance, Risks, Rewards, Repetition.
  - ASSIST those ready to make a quit attempt:
    - Set a quit date. Quit date abstinence is a strong predictor of long-term success [C].
    - Give advice on quitting and provide supplementary materials.
    - Refer to more intensified counseling as appropriate.

- Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies and bupropion hydrochloride have both been proven effective [A].
- ARRANGE follow-up either with phone call or office visit.
  - Prevent relapse by congratulating successes and reinforcing reasons for quitting.
  - Assess any difficulties with pharmacologic therapy.

#### Definitions:

Levels of evidence:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

#### CLINICAL ALGORITHM(S)

Algorithms are provided in the original full-text guideline for clinician's actions to help patients quit smoking.

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size. The type of evidence for each recommendation is given in brackets following the recommendation (see "Major Recommendations").

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Effective interventions and strategies are provided that could help health care providers assist patients in smoking cessation.

#### POTENTIAL HARMS

Side effects of medications may occur and include the following:

- Transdermal nicotine patch. Skin reactions such as pruritus, edema, rash; sleep disturbance.
- Nicotine gum (polacrilex). Jaw fatigue, hiccups, belching, and nausea.
- Nicotine nasal spray. Nasal irritation/rhinorrhea (98% of patients), sneeze, cough. Severity of effects decrease after first week.
- Nicotine inhaler. Cough, mouth and throat irritation.

- Bupropion hydrochloride SR (Zyban®). Insomnia and dry mouth.
- Clonidine. Dry mouth and sedation.
- Nortriptyline. Dry mouth.

No studies have addressed the safety of nicotine replacement therapy or bupropion hydrochloride in pregnancy. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: Zyban® – category B\*, nicotine transdermal, spray and inhaler – category D\*, nicotine gum – category C\*.

Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.

## CONTRAINDICATIONS

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Bupropion hydrochloride SR (Zyban®) is contraindicated in patients with seizure disorder, major head trauma, eating disorders, and in patients on Wellbutrin® (bupropion hydrochloride) or monoamine oxidase (MAO) inhibitors. It should be used with caution in patients with predisposition to seizure (i.e., head trauma, alcohol withdrawal, concomitant use with other medications that lower seizure threshold – antipsychotics, antidepressants, theophylline.)

## QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

#### Organizing a Health Care Site to Support Smoking Cessation Efforts

Successful intervention programs require coordinated efforts at a health care site. Several clinic personnel may be involved in operational steps of "Asking, Advising, Assisting, and Arranging". Clinicians should help their clinics develop a coordinated plan of tasks and who will perform them. Some specific areas for planning include:

Record smoking status. Institute an office system to identify all smokers:

- Identify where smoking status will be recorded. Options include making smoking status part of vital signs, placing smoking status stickers on charts, or including smoking status on a section of the problem summary list.
- Determine who will routinely ask and record the information.
- Instruct staff regarding their roles in documentation.
- Reinforce the value of the documentation.

Smoking cessation follow-up. Develop a system and assigned role(s) at the health care site to:

- Ensure the availability of patient education materials on smoking cessation.
- Establish procedures for clinicians to provide a designated follow-up person with information on patients who are setting quit dates. Coordinate follow-up phone calls in conjunction with quit dates.
- Provide follow-up cessation counseling as needed at subsequent visits.
- Refer patients to more intensive counseling programs for smoking cessation, as needed.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p. [1 reference]

### ADAPTATION

The guideline was adapted from the Public Health Service guideline: Treating tobacco use and dependence. A clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. Clinical Practice Guideline.

### DATE RELEASED

1998 Sep (updated 2001 Feb)

### GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

#### SOURCE(S) OF FUNDING

University of Michigan Health System

#### GUIDELINE COMMITTEE

Smoking Cessation Guideline Team

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

None of the members of the Smoking Cessation Guideline Team nor the consultant have relationships with commercial companies whose products are discussed in this guideline. (The members of these teams are listed on the front page of the original guideline document.)

#### GUIDELINE STATUS

This is the current release of the guideline. It updates a version previously published by the University of Michigan Health System (UMHS) in 1998.

An update is not in progress at this time.

#### GUIDELINE AVAILABILITY

Electronic copies: Available for download (in Portable Document Format [PDF]) from the [University of Michigan Health System Web site](#).

#### AVAILABILITY OF COMPANION DOCUMENTS



None available

## PATIENT RESOURCES

The following patient education information is available:

- How to use your nicotine product. Ann Arbor (MI): University of Michigan Health System, 1998.
- Tips for quitting smoking. Ann Arbor (MI): University of Michigan Health System, 1998.

Print copies: Available from the University of Michigan Health System, GUIDES, 300 North Inglass, Room 7A10, Ann Arbor, MI 49109-0826; Telephone: (734) 936-9771; Fax: (734) 615-0062; e-mail: [gdlnoversight@umich.edu](mailto:gdlnoversight@umich.edu).

## NGC STATUS

This summary was completed by ECRI on January 11, 2002. The information was verified by the guideline developer as of February 8, 2002.

## COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is copyrighted by the University of Michigan Health System (UMHS).

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